

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Jiang	Art Unit:	1745
Serial No.:	10/711,154	Examiner:	Timothy M. Speer
Filed:	08/27/2004		
Docket No.:	A382-USA		
For:	Material and Method to Prevent Low Temperature Degradation of Zirconia in Biomedical Implants		

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Commissioner for Patents
PO Box 1450
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PRE-APPEAL BRIEF

Dear Sir:

**Whether the Limitation to Ion Beam Assisted Deposition is a
Limitation for Patentability?**

The first issue raised in this Pre-Appeal Brief is whether a claim limitation for purposes of infringement analysis in a product-by-process claim is a limitation for ex parte prosecution? Applicant's claim 1 is:

A degradation resistant composition of matter for use in living tissue,
comprising:

an yttria-stabilized tetragonal zirconia polycrystal substrate;
a coating of alumina deposited on the substrate, said coating being
deposited by ion beam assisted deposition in the presence of the
substrate; and wherein
said coating has a total porosity of less than about 1.0 percent.

It is undisputed [the Examiner consistently recognizes the critical phrase as

a limitation, see for example Office Action 5/9/06, page 2, last paragraph] that the phrase "ion beam assisted deposition" is a process limitation. However, Applicant argues the effect of this limitation in the Amendment of 12/06/05 [page 3], citing that "process terms in product-by-process claims served as limitation in determining infringement." *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 835, 846-47 (Fed. Cir. 1992). The Examiner states [Office Action 5/9/06, page 4, para 9] that Applicant's reliance on Atlantic Thermoplastic is misplaced and that Applicant's argument is "...not persuasive, for, as applicant is well aware, in *Atlantic Thermoplastic*, the court was addressing product-by-process claims in the context of infringement and NOT ex parte prosecution." Applicant contends on appeal that the undisputed limitation is a claim limitation for all purposes, thereby making claim 1 allowable over the prior art.

Whether Schubert Teaches Applicant's Invention?

The second issue is whether Schubert (H. Schubert, N. Claussen, and M. Ruhle, *Surface Stabilization of Y-TZP*, British Ceramic Proceedings, **34** 157-160 (1984)) teaches a coating to protect the ceramic from conversion?

The Examiner states [Office Action 5/9/06, page 5, para 10] "Finally, applicant argues that the applied prior art does not teach a "layer" as presently claimed. This is not persuasive. Following processing as disclosed in the prior art, a layer is formed on the surface of the Y-TZP substrate." The Examiner's statement is clearly wrong. Schubert does not teach a coating, they teach an *in situ* conversion of the Y-TZP substrate by heating it in a bed of packed oxide powder, viz. Y_2O_3 , CeO_2 , MgO or CaO . By this process, Schubert teaches that a converted protective layer of Y_2O_3 -stabilized cubic ZrO_2 grains form on the surface of the Y-TZP substrate. Schubert does not teach a coating at all and therefore does not teach an ion beam assisted deposition (IBAD) coating of Al_2O_3 as taught by Applicant. Schubert merely teaches that yttria can be diffused into the surface of the substrate to phase stabilize it.

The Examiner misstates and misconstrues Applicant's argument that Schubert does not teach Applicant's invention. Applicant states [Amendment, 12/6/05, page 4, second full paragraph] that, "This is done *in situ* converting of the

surface of the compact and not by applying a coating and not by employing a coating process. Schubert does not teach a coating at all." [emphasis added] A word search of Applicant's amendment does not find the terms "layer" or "layers" at all. The Examiner misstates Applicant's argument, as quoted above, when it is claimed that the Applicant argues the prior art does not teach a "layer".

Applicant concedes that Schubert teaches a layer, but a "layer" is not a "coating". The terms are distinct and are not equivalent. In the case of Schubert, substrate surface conversion by diffusion creating a phase-stable layer is taught. On the other hand, Applicant teaches a distinct coating of alumina formed on the surface of the substrate.

Simply put, Applicant teaches a stabilized zirconia body that is coated with a distinct alumina coating. Schubert teaches a stabilized zirconia body that has a surface layer that is yttria-rich. The products of the two teachings are materially different and are readily distinguished from each other.

Whether Schubert Teaches an Alumina Coating?

Schubert is silent as to the use of Al_2O_3 to protect the zirconia substrate. Schubert does not teach the use of Al_2O_3 at all. Again, Schubert does not teach the invention of Applicant.

Whether Schubert is Applicable at all as Prior Art?

There is much discussion in the Office Action of May 9, 2006, paragraph 4 beginning on page 2, about Schubert and then Hida stabilizing the zirconia. These approaches are inapplicable to the instant application. The Applicant does not form a phase stable zirconia but rather starts with a phase-stable zirconia and then coats the yttria-stabilized tetragonal zirconia polycrystal substrate [i.e., the stable zirconia] with an inert and hermetic coating of alumina by ion beam assisted deposition. The alumina is not used to change or combine with the zirconia, it forms a distinct coating that has been shown to protect the underlying substrate.

Whether Hida is Applicable as Prior Art?

The Examiner [Office Action of 5/9/06, page 3, second full paragraph] states, "Hida teaches that alumina is a stabilizing oxide with respect to zirconia

and is functionally equivalent to magnesia, ceria, calcia and yttria."

Applicant does not teach phase stabilization of zirconia with alumina, even if alumina is an oxide which stabilizes zirconia. [It is well known to those skilled in the art that alumina can be combined with zirconia to form alumina-toughened zirconia, however alumina does not phase-stabilize zirconia, contrary to the Hida reference]. Applicant teaches an alumina coating, not alumina-phase stabilization of zirconia.

Applicant argues that claim 1 is therefore allowable as submitted and that the dependent claims are allowable as further limitation on an allowable claim.

Respectfully submitted,

6/8/06

Date



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